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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,153	09/29/2005	Annette Martin	UTSG:272US	7019
32425 7590 09/07/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/520,153

**Applicant(s)**

MARTIN ET AL.

**Examiner**

Stacy B. Chen

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicant's preliminary amendment filed January 3, 2005, is acknowledged and entered. Claims 1-30 are pending and subject to the following restriction.

***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1, 2, 17, 18, 21 and 24-26 link(s) inventions I, II and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 17, 18, 21 and 24-26. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections

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over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- Group I, claims 3-16, drawn to an isolated polynucleotide comprising a chimeric GB virus B (GBV-B) polynucleotide encoding a virus, wherein at least one, but not all of domain I, II, III or IV of the 5' non-translated region (NTR) is from Hepatitis C Virus (HCV) 5' NTR. *If Group I is elected, further restriction is required. Embodiments A, E, F and G are related. Embodiments B, E, H, I and K are related. Embodiments C, F, H, J and K are related. Embodiments D, I, J and K are related. As an example, if Applicant elects A, claim 3 and claim 4 will be examined; claims 5-16 will be withdrawn from consideration. Should claims 3 and 4 be found allowable during prosecution, the other related embodiments of E, F and G will be rejoined. Applicant must elect one of the following embodiments.*

A. Domain I of the 5' NTR, claim 4

B. Domain II of the 5' NTR, claim 5

C. Domain III of the 5' NTR, claims 6, 7, 22 and 23

D. Domain IV of the 5' NTR, claim 8

E. Domains I and II of the 5' NTR, claim 9

F. Domains I and III of the 5' NTR, claim 10

G. Domains I and IV of the 5' NTR, claim 11

H. Domains II and III of the 5' NTR, claim 12

I. Domains II and IV of the 5' NTR, claim 13

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J. Domains III and IV of the 5' NTR, claim 14

K. Domains II, III and IV of the 5' NRT, claims 15 and 16

- Group II, claim 19, drawn to an isolated polynucleotide comprising a chimeric GB virus B (GBV-B) polynucleotide encoding a virus, further comprising at least part of a structural protein coding region of HCV.
- Group III, claim 20, drawn to an isolated polynucleotide comprising a chimeric GB virus B (GBV-B) polynucleotide encoding a virus, further comprising at least part of a non-structural protein coding region of HCV.

-----**End of Linking Claims**-----

- Group IV, claims 27-30, drawn to a method for identifying a compound active against a viral infection.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the instant invention shared by Groups I-IV is a chimeric GBV-B polynucleotide sequence that encodes a virus. The prior art teaches this technical feature, as detailed below. Thus, the claims lack unity of invention.

Simons *et al.* (*PNAS USA*, 1995, 92:3401-3405, "Simons") teach an isolated 3' sequence of the GBV-B genome. Moreover, Simons *et al.* inherently teach that which is claimed since the GBV-B genome (RNA) is very closely related to HCV. Thus, GBV-B inherently comprises at least part (any part) of a 5' NTR sequence derived from a HCV 5' NTR, for example. Applicant

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is reminded that the "part" is inherently taught irrespective of the source. That is, the reference appears to disclose the same isolated polynucleotide as claimed by applicants. Although the reference does not disclose the HCV 5' NTR, the structural protein coding region of HCV, or the non-structural protein coding region of HCV, i.e. derived from HCV, the GBV-B genome is expected to contain "part" of the genome which is identical to the HCV genome. Thus, the production of a polynucleotide by a particular process (splicing GBV-B/HCV) does not impart novelty or unobviousness to a polynucleotide when the same polynucleotide is taught by the prior art. This is particularly true when the process and/or the source of the polynucleotide do not change the properties of the polynucleotide in an unexpected manner. Therefore, even if a particular process used to prepare a polynucleotide is novel and unobvious over the prior art, the polynucleotide *per se*, even when limited to the particular process, is unpatentable over the same polynucleotide taught by the prior art.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

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inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 8-21-2007  
Primary Examiner, TC1600